UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,266	07/11/2001	Olivier de Lacharriere	016800-454	8334

7590 11/05/2002

Norman H. Stepno, Esquire
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/05/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,266	Applicant(s) De LACHARRIERE et al.
	Examiner Michele Flood	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 19, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above, claim(s) *17* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I, Claims 1-16, in Paper No. 5 is acknowledged. The traversal is on the grounds that the restriction is inaccurate because the process of Group II cannot be practiced with another materially different product than the product of Group I, since the claimed method explicitly defines administering an effective amount of an "intimate admixture of vitamin A, vitamin C, vitamin E and zinc and selenium values." Applicant further argues that the search for both inventions would not be burdensome. This is not found persuasive because the two groups are directed to two different inventions: the invention of Group I is directed to a cosmetic/pharmaceutical composition comprising recited ingredients, whereas the invention of Group II is directed to a method of using a cosmetic/pharmaceutical composition comprising recited ingredients. Furthermore, it is unclear as to how Applicant defines an "intimate admixture". The specification does not define the phrase and one of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation other than that the ingredients of the claimed composition are in close proximity to one another.

As set forth in the previous Office action, the process for using the composition as claimed can be practiced with another materially different product, contrary to the urging of Applicant. For instance, in US 6156899, Galey et al. teach a method for inducing/stimulating

hair growth and/or retarding hair loss comprising the administration of N-aryl-2-hydroxyalkylamido compounds; in US 6149933, Nelson teaches a method for inducing repigmentation of the hair comprising the administration of a composition comprising copper salt, para-aminobenzoic acid or salts thereof, pantothenic acid or salts thereof, and vitamin B; in US 5068315, Buultjens et al. teach a method of increasing the diameter of the hair strand, and/or lengthening the hair strand, and/or preventing, retarding, or arresting the process of hair loss comprising the administration of polypeptides; and, in US 5827510, Mesquitta teaches a method of improving the quality of hair comprising the administration of a composition comprising castor oil, water and glycerin. Moreover, the product as claimed can be practiced in a materially different process such as providing nutritional vitamins and minerals to an individual for the purpose of maintaining health.

Thus, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are rendered vague and indefinite by the phrase "intimate admixture" because it is unclear as to what constitutes an "intimate admixture". Other than the mere mentioning of the phrase on page 7, line 6, paragraph [0042] of the instant application, Applicant has not provided a definition of the meaning of the phrase to apprise one of ordinary skill in the art as to how one would interpret the meaning of the phrase. The Office further notes that the term is only related to an admixture of zinc and selenium values, e.g., "for example intimate admixture of zinc sulfate and sodium selenite." Since, the specification does not define the phrase and one of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation other than that the ingredients of the claimed composition are in close proximity to one another and are mixed together, the lack of clarity renders the claim ambiguous, especially in view of Applicant's arguments that the "intimate admixture" of ingredients is a critical feature of the claimed invention in Paper No. 5 ("Response to Restriction Requirement", page 2, lines 8-14).

With regard to Claim 13, an apparent typographical error, i.e., "by any Claim 8" renders the claim vague and indefinite; thus, it is unclear as to the subject matter Applicant intends to direct the subject matter of the invention.

Claim 12 is rendered vague and indefinite by the phrase "a synthetic molecule or association exhibiting enzymatic activity" because it is unclear as to the subject matter Applicant intends to direct the invention. The claim appears to be a literal translation into English from a foreign document having grammatical and idiomatic errors.

Claim 14, line 2, is rendered indefinite by the phrase "vitamin A being present as beta-carotene equivalent thereof" because it is unclear as to what is "a beta-carotene equivalent thereof" or as to what "thereof" refers. It would appear that Applicant intends to direct the subject matter of the claimed invention to wherein the vitamin A is present as a beta-carotene. And, as such, for the purposes of examination, the claims have been examined as reading "wherein the vitamin A is present as a beta-carotene".

Claim 15 recites the limitation "beta-carotene" in line 2. The claim lacks clear antecedent basis for this limitation.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Launches (U).

Applicant claims a cosmetic/pharmaceutical composition for promoting hair regrowth and/or retarding hair loss, and/or for increasing the mean diameter of strands of hair; and/or for decreasing the heterogeneity of the diameters of strands of hair, and/or for increasing hair density, and/or for improving the quality and/or the appearance of a head of hair, and/or for inducing repigmentation of the hair comprising a thus effective amount of intimate admixture of vitamin A, vitamin C, vitamin E, and zinc and selenium values. Applicant further claims the cosmetic/pharmaceutical composition as defined by any of Claims 1 to 6 comprising dose range amounts of claimed ingredients. Applicant further claims a composition, further comprising iron, magnesium, copper and/or manganese values, or combination thereof. Applicant further claims the cosmetic/pharmaceutical composition as defined by any of Claims 1 to 6, formulated for oral administration, in a cosmetically/pharmaceutically acceptable vehicle, diluent or carrier therefor. Applicant further claims the cosmetic/pharmaceutical composition as defined by any of

Claims 1 to 6, the vitamin A being present as a beta-carotene equivalent. Applicant further claims the cosmetic/pharmaceutical composition as defined by Claim 14, comprising about 0.6 mg to about 18 mg of beta-carotene. Applicant further claims a composition as defined by any of Claims 1 to 6, formulated as a drinkable solution, syrup, tablets, or capsules.

Drug Launches teaches OCUVITE™, which comprises zinc oxide (40 mg), copper oxide (2 mg), vitamin C (60 mg), vitamin E (30 IU or 30 mg), vitamin A (as beta-carotene, 5000 IU or 3 mg), and selenium (40 mcg). The active ingredients are combined with a pharmaceutically acceptable carrier in the making of tabs for oral administration.

According to a Bausch & Lomb/Pharmacovigilance representative, the referenced composition contained vitamin A as beta-carotene at the time of the cited reference, as evidenced by the communication received from Bausch & Lomb/ Pharmacovigilance (dated October 31, 2002) re Product Code 4550, OCUVITE® Vitamin and Mineral Supplement, Tablets.

The conversion factor for the international unit (IU) of vitamin A as beta-carotene is set forth as follows: 5000 IU of vitamin A is equivalent to 3 mg of beta-carotene (see page 3 of " A Quick Vitamin and Mineral Guide"; **http://www.aabhealth.com/quickguide).** The conversion factor for the international unit (IU) of vitamin E as dl-alpha tocopheryl acetate is set forth as follows: 1 IU of vitamin E is equivalent to 1 mg of vitamin E (see "Ask a Scientist"; http://www.newton.dep.anl.gov/askasci/chem99/chem99136).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not

patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Thus, the cited reference is deemed to anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kronnie (A1) in view of Cauwenbergh (A), Proctor (B) and Nishida et al. (N, JPO translation provided attached hereto).

Applicant's claimed invention of Claims 1, 7 and 11 was set forth above. Applicant further claims the cosmetic/pharmaceutical composition as defined by Claim 8 comprising dose range amounts of claimed ingredients. Applicant further claims a composition as defined by any of Claims 1 to 6 formulated for topical application, in a cosmetically/pharmaceutically acceptable vehicle diluent or carrier therefor. Applicant further claims the cosmetic/pharmaceutical composition as defined by any of Claims 1 to 6, further comprising an

additional antioxidant, a catalase, a peroxidase, a synthetic molecule or association exhibiting enzymatic activity, a sulfur-containing amino acid, or combination thereof.

Kronnie teaches a topical composition comprising vitamin A acetate, vitamin E acetate, vitamin C, zinc, and iron phosphate to stimulate the regrowth of hair. The composition taught by Kronnie was effective in promoting hair growth in previously bald people and in people having hair loss.

The teachings of Kronnie are set forth above. Kronnie does not teach a composition comprising selenium, further comprising the ingredients of Claim 12 (i.e., antioxidant, catalase, peroxidase, a synthetic molecule, a sulfur-containing amino acid), and the instantly claimed dose amounts of vitamin A, vitamin C, vitamin E, zinc and selenium. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by Kronnie and to optimize the amounts of the ingredients comprising the composition taught by Kronnie to provide the claimed invention because at the time the invention was made selenium, antioxidants, catalase, peroxidase, synthetic molecules and sulfur-containing amino acids were known to have the claimed functional effect for promoting hair regrowth and/or retarding hair loss, as evidenced by the teachings of Cauwenbergh, Proctor and Nishida. Firstly, Cauwenbergh teaches a topical composition comprising an anagen hair-inducing agent, e.g., selenium sulfide, which reduces the shedding of hair and increases the diameter of a hair shaft, in Column 2, lines 24-43. In Column 4, lines 32, Cauwenbergh further teaches zinc pyrithione as a hair shedding reductant, also. The anagen-hair inducing agents taught

by Cauwenbergh are in an amount of about 1% of the hair compositions. See Column 5, lines 58-60 and claims. Secondly, Proctor teaches compositions comprising either ascorbates (a vitamin C salt) or sulfhydryls such as the sulfur-containing amino acids cysteine, N-acetylcysteine, glutathione, etc., which stimulate hair growth, increase the rate of hair growth, increase hair diameter, follicular neogenesis, and inhibit hair loss, in Column 1, lines 34-67 to Column 2, lines 1-61. In Column 2, lines 66-67 bridging Column 2, lines 1-10, Proctor teaches the dose amounts of sulfur-containing amino acids and ascorbates required to provide the disclosed beneficial effects. Thirdly, Nishida teaches a hair growth tonic comprising effective dose amounts of carotenes, which is additionally formulated with effective amounts of 1-hydroxy-2-pyridone and a plant extract having anti-inflammatory, blood circulation-promoting and/or 5 and alpha; -reductase-inhibitory activity. In [0021] of the translation, Nishida teaches that the referenced composition can be blended with other cell activation components such as vitamin A, ascorbic acids (vitamin C), and tocopherols (vitamin E). At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to add the instantly claimed ingredients to the composition taught by Kronnie and to adjust the instantly claimed ingredients to provide the instantly claimed composition because Cauwenbergh teaches that selenium and zinc reduce hair shedding and that the referenced compositions are not only effective in alleviating symptoms indicative of unhealthy hair and scalp, but also are effective in treating dandruff and seborrheic dermatitis when topically applied (see Column 2, lines 43-46); Proctor

teaches topical hair compositions comprising ascorbates (a vitamin C salt) that stimulate hair growth (see EXAMPLE 2) and topical hair compositions comprising sulfur-containing amino acids such as cysteine and N-acetylcysteine that stimulate hair growth, inhibit hair loss or alopecia from progressing (see Column 2, lines 46-61 and EXAMPLE 1); and, Nishida teaches that a composition for topical application to the hair comprising beta-carotene combined with cell activation and blood-circulation promoting components has excellent hair growth-promoting activity. Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the amounts of the ingredients used in the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts of the claimed ingredients to provide a composition with the claimed functional effect for promoting hair regrowth and/or retarding hair loss. Hence, the claimed invention is no more than the routine optimization of a result effect variable.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable

phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood

MCF

November 4, 2002